Guidepath

DEC 1 3 2012

510(k) SUMMARY

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT	Guidepath Medical, Inc. 2621 Ridgepoint Dr. Suite 100 Austin, TX 78754 USA
CONTACT	Mitchell Tatum President, CEO Tel: 512.638.2000 mitchell@guidepathmedical.com
DATE PREPARED	May 4th, 2012
PRODUCT NAME	Charlie Guidewire
COMMON NAME	Guide Wire
CLASSFICATION NAME	Wire, Guide Catheter
DEVICE CLASSIFICATION	Class II per 21 CFR 870.1330
PRODUCT CODE	DQX – Catheter Guide Wire
PREDICATE DEVICE	Terumo – Radifocus Guidewire (K863168) Argon Medical – Guidewires (K841926) Abbott – Balance Middleweight Guidewire (K101011)

DESCRIPTION OF THE DEVICE

The Charlie Guidewire is a steerable guidewire that is compatible with .035" catheters and devices. Lengths are available from 70cm to 280cm. The guidewire is constructed from a Nitinol core wire with a polymer jacket. The jacket is coated with a hydrophilic polymer. The distal tip is atraumatic, and available in straight or various angled configurations. The main body is available in varying stiffness configurations. The device will be provided sterile and intended for one-time use. Product has a 2-year shelf life.

INDICATIONS FOR USE

The Charlie guidewire facilitates the introduction and placement of catheters and interventional devices to the desired anatomical location during diagnostic or interventional procedures.

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TECHNICAL CHARACTERISTICS

The Charlie Guidewire consists of a Nitinol core wire, an atraumatic distal tip, radiopaque polymer jacket, and a hydrophilic coating. The Charlie Guidewire is similar in dimensions and operating principles as the predicates. In addition, the materials used are similar to the predicates, and are commonly used materials in medical device applications. Comparison of the Charlie Guidewire and predicate devices show that the technological characteristics, such as the design, intended use, and performance data are substantially equivalent to the current marketed predicate devices.

PERFORMANCE DATA

Enclosed within this submission are performance data that demonstrate that the Guidepath Charlie Guidewire family meets all predetermined performance criteria. All components that are in contact with the patient have a known history of use in medical devices and are tested and proven to be biocompatible and acceptable for vascular use. Bench testing per applicable reference documents was completed comparing Charlie Guidewires to the predicates or to known standards for guidewire performance. This 510(k) includes the mechanical and functional bench testing that demonstrates the Charlie Guidewire performs as intended and is Substantially Equivalent to the predicates.

The biocompatibility of the Charlie Guidewires has been proven through applicable biocompatibility testing performed on finished, sterile devices. This 510(k) includes the results of the biocompatibility testing.

Performance Tests	Biocompatibility Testing
Resistance to flexure (flexing test)	Cytotoxicity
Tip resistance to fracture (fracture test)	Sensitization
Radiopacity	Irratation/Intracutaneous
Catheter compatibility	Pyrogenicity
Coating adherence	Systemic Injection
Torque strength	Thrombosis
Torque response	PTT
Coating lubricity	Hemolysis
Tip stiffness	Compliant Activation
Tensile	Coating/volatile residue

SUMMARY/CONCLUSION

The Guidepath Charlie Guidewire characteristics are substantially equivalent to the specified predicate devices and other currently marketed devices for the same indication for use. Performance test results demonstrate that any minor differences do not impact device performance as compared to the predicates and raise no new safety or efficacy concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Guidepath Medical, Inc.
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DEC 1 3 2012

Re: K121398
Trade/Device Name: Charlie guidewire (regular), charlie guidewire (stiff)
Regulation Number: 21 CFR 870.1330
Regulation Name: Charlie Guidewire
Regulatory Class: Class II
Product Code: DQX
Dated: December 7, 2012
Received: December 11, 2012

Dear John Mitchell Tatum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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INDICATIONS FOR USE

510(k) Number (if known):

DEVICE NAME: Charlie Guidewires

INDICATIONS FOR USE: To facilitate the introduction and placement of catheters and interventional devices to the desired anatomical location during diagnostic or interventional procedures.

Prescription Use___X___ AND/OR Over the Counter_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K121398